

Title: DIVISION SPONSOR/CUSTOMER COMPLAINTS	Number: D65-14-02	Revision No.: OD	Effective Date: 31 JAN 97
	Prepared By: Thomas J. Underwood	Approved By: Thomas S. Dodson	Page: 1 OF 2

31 January 1997

STANDARD OPERATING PROCEDURE D65-14-02

From: D65

To: D65 Division

Subj: DIVISION SPONSOR/CUSTOMER COMPLAINTS

Ref: (a) SOP D65-14-01 Division Corrective and Preventive Actions

(b) SOP D65-13-01 Division Control of Nonconforming Product

1. Purpose. To establish a system and provide instructions for the processing sponsor/customer complaints, and handling of products returned by sponsor/customers.

2. Scope and Application. This procedure applies to sponsor/customer complaints and returned products caused by problems with product quality, product support and servicing, and delivery.

3. Policy. The primary organizational point of contact for receipt of all sponsor/customer complaints is Division Quality Assurance (QA). Any complaints received by Branches and staff functions will be immediately routed to QA.

4. Procedure. The following procedures will be followed regarding receipt and handling of sponsor/customer complaints.

a. Receiving Sponsor/Customer Complaints - All mailed and faxed sponsor/customer complaints will be delivered to QA. Phone calls regarding complaints will also be routed to QA. Complaints received by phone will be documented in a memo to QA immediately after the conversation with the complaining sponsor/customer.

b. Recording Sponsor/Customer Complaints - All sponsor/customer complaints (including memos documenting complaints received by phone) are recorded in the Sponsor/Customer Complaints Log maintained by QA. The record includes the name of the sponsor/customer, reference to and/or description of the task\order, a short description of the nature of the complaint, and processing history of the complaint. Processing history of sponsor/customer complains and previous corrective actions taken are and will continue to be recorded in the Sponsor/Customer Complaints Log. This Log is located in the QA area.

c. Processing Sponsor/Customer Complaints - When a complaining sponsor/customer is also returning defective or otherwise unsuitable products, the complaint will be immediately reported to the cognizant ("owning") Program Manager and to QA. QA and the "corrective action"

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branch will evaluate and process the returned products in accordance with Procedure SOP-13-01, Control of Nonconforming Product, and report back the results of its investigation and corrective action taken, if required, to all internal persons involved and to the sponsor/customer. QA will prepare and send the response back to the sponsor/customer.

THOMAS S. DODSON